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GAIL WARDWELL
Typed or Printed Name of Person Mailing Paper or Fee

Gail Wardwell
Signature of Person Mailing Paper or Fee

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

KURTZMAN et al.

Serial No.: CON of 09/309,042 Group Art Unit: To be Assigned

Filing Date: on even date herewith Examiner: To be Assigned

Title: METHODS FOR DELIVERING DNA TO THE BLOODSTREAM USING RECOMBINANT ADENO-ASSOCIATED VIRUS VECTORS (as amended)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please enter the following amendments prior to prosecution.

Amendment

In the Title:

Please replace the current Title with the following:

--METHODS FOR DELIVERING DNA TO THE BLOODSTREAM USING RECOMBINANT ADENO-ASSOCIATED VIRUS VECTORS--.

In the Specification:

Please amend the specification as follows:

Before the first line of the application, please insert the following:

--This application is a continuation of U.S. Patent Application Serial No. 09/309,042, filed May 10, 1999, which is a continuation of U.S. Patent Application Serial No. 09/226,989, filed January 7, 1999, which is a continuation of U.S. Patent Application Serial No. 08/588,355, filed January 18, 1996, now U.S. Patent No. 5,858,351, from which applications priority is claimed pursuant to 35 U.S.C. §120--.

In the Claims:

Please cancel claims 1-22 without prejudice and without disclaimer and add the following new claims:

--23. A method of administering recombinant adeno-associated virus (AAV) virions into the bloodstream of a mammalian subject, said method comprising:

(a) providing AAV virions comprising a selected gene operably linked to expression control elements that provide for transcription and translation of the selected gene in a desired host cell *in vivo*; and

(b) delivering said recombinant AAV virions to the bloodstream, whereby said selected gene is expressed at a level which provides a therapeutic effect in the mammalian subject.

24. The method of claim 23, wherein the AAV virions are delivered intraarterially.

25. The method of claim 23, wherein the selected gene encodes a therapeutic protein useful for treating a blood disorder.

26. The method of claim 25, wherein the therapeutic protein is erythropoietin.

27. The method of claim 25, wherein the blood disorder is hemophilia.

28. The method of claim 23 wherein said protein is secreted.

29. A method of expressing a therapeutically effective amount of a protein in a mammalian subject, said method comprising:

administering into the bloodstream of said subject a pharmaceutical composition which comprises (a) a pharmaceutically acceptable excipient; and (b) recombinant AAV virions comprising a selected gene operably linked to expression control elements that provide for transcription and translation of the selected gene in a desired host cell *in vivo*, whereby said virions transduce cells in said subject, and said selected gene is expressed by the transduced cells at a level which provides for a therapeutic effect in said subject.

30. The method of claim 29, wherein the pharmaceutical composition is delivered intraarterially.

31. The method of claim 29, wherein the selected gene encodes a therapeutic protein useful for treating a blood disorder.

32. The method of claim 31, wherein the therapeutic protein is erythropoietin.

33. The method of claim 31, wherein the blood disorder is hemophilia.

34. The method of claim 29 wherein said protein is secreted.--

REMARKS

Applicants have amended the specification to include a claim for priority and to reflect the continuing information with respect to this application.

Claims 1-22 have been canceled without prejudice and disclaimer. Applicant expressly reserves the right to bring the claims again in a subsequent, related application.

New claims 23-34 have been added and are directed to methods of administering recombinant adeno-associated virus (AAV) virions into the bloodstream of a mammalian subject (claims 23-28); and methods for expressing a therapeutically effective amount of a protein in a mammalian subject (claims 29-34). Support for the new claims may be found throughout the specification, particularly at page 10, lines 29-34; page 16, lines 8-18; page 20, lines 33-34; page 30, line 33; page 40, lines 13-15; and page 44, lines 20-33.

Accordingly, no new matter has been added by way of the new claims, and the entry thereof is respectfully requested.

Respectfully submitted,

Date: 1/4/01 By: _____
Roberta L. Robins
Registration No. 33,208

Customer No. 20855
ROBINS & ASSOCIATES
90 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 325-7812
Fax: (650) 325-7823